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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,692	07/09/2003	Jodi Nelson	47-003	1639

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EXAMINER	
CORNET, JEAN P	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
09/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,692	NELSON, JODI	
	Examiner	Art Unit	
	JEAN CORNET	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/01/2006, 10/11/2007, 11/12/2008, 01/02/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 10/11/2007 and 11/12/2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

2. Applicant's arguments filed 09/01/2006 have been fully considered. Rejections and objections not reiterated form previous Office Action is hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

3. Claims 1-13 are currently under examination and are the subject of this office action. Claims 14-36 are cancelled by applicant.

4. The Affidavits filed on 04/20/2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Roberts-Lewis et al. of U.S. Patent No. 5,430,039 in view of Di Rocco et al. of U.S. Patent No. 5,496,836 reference. The 5,430,039 and 5,496,836 reference are statutory bar under 35 U.S.C. 102(b) and thus cannot be overcome by an affidavit or declaration under 37 CFR 1.131.

5 The substitute copies of the publications in the information disclosure statement (IDS) submitted on 09/01/2006 is being considered by the examiner.

6. **The Rejection Under Section 112, Second Paragraph**

Applicant's arguments, see Page 6, filed 09/01/2006, with respect to the rejection under 35 USC 1st and 2nd Paragraph have been fully considered and are persuasive. The rejections of 3 and 9 have been withdrawn due to amendment.

7. **The Rejection Under Section 103(a)Over Roberts-Lewis et al.and Di Rocco et al.**

Applicant's arguments, with respect to the rejection under 35 USC 103(a) have been fully considered but they are not persuasive.

Applicant argues that **(1)** the "039 Patent does not enable the treatment of Parkinson's disease or other neurological condition with chloroquine compounds **(2)** Di Rocco et al patent also does not enable the treatment of Parkinson's disease using cimetidine and **(3)** there is no motivation in the reference nor in the art as a whole for combining these references to formulate an obviousness rejection and therefore there in not properly cited as the basis of an obviousness rejection. In response, it is noted that there is a rebuttable presumption of operability/enablement with respect to prior art, regardless of what type of prior art is at issue. See MPEP 2121. A reference is presumed operable until applicant provides facts rebutting the presumption of

operability. *In re Sasse,* 629 F.2d 675, 207 USPQ 107 (CCPA 1980). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. See MPEP 2121.01. "Even if a reference discloses an inoperative device, it is prior art for all that it teaches." *Beckman Instruments v. LKB Produkter AB,* 892 F.2d 1547, 1551, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989). When a prior art reference merely discloses the structure of the claimed compound, evidence showing that attempts to prepare that compound were unsuccessful before the date of invention will be adequate to show inoperability. *In re Wiggins,* 488 F.2d 538, 179 USPQ 421 (CCPA 1971). In this case, the combined '039 Patent and Di Rocco reference teach the claimed chloroquine combined with cimetidine for the treatment of Parkinson's disease as discussed previously. This teaching constitutes enabling prior art for the claimed invention since the public was in possession of the claimed invention before the date of the invention. Further, the Court has held that when a prior art reference merely discloses the structure of the claimed compound, evidence showing that attempts to prepare that compound were unsuccessful before the date of invention will be adequate to show inoperability. *In re Wiggins,* 488 F.2d 538, 179 USPQ 421 (CCPA 1971). It is not the case here, because the combined reference teaches the method of treating Parkinson's disease that is similar to that disclosed in the instant application. Finally, it is well established that the arguments of counsel cannot take a place of evidence in the record. *In re Schulze,* 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler,* 116 F.3d 1465, 43 USPQ2d 1362 (Fed.Cir. 1997}.

In addition, in response to no motivation to combine the reference, as stated in the previous Office Action, page 6, It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose... .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven,* 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Moreover, it is well within the level of the skilled artisan to determine optimal modes and methods of administration as well as the procedures for making pharmaceutical compositions having the optimum therapeutic dosage while minimizing adverse and/or unwanted side effects.

Applicant also argues that the '836 patent does not enable and in fact teaches against treatment of Parkinson's disease using cimetidine. The '836 patent clearly states in the abstract that H2 antagonists including cimetidine can be used in the treatment of movement disorders where the movement disorder is a component of Parkinson's disease (see office action, page 6). In fact it is the combination of the '836 patent and the '039 patent that constitutes the rejection, not the '836 alone. Therefore the rejection is maintained.

Claims 1-13 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Roberts-Lewis et al. of U.S. Patent No. 5,430,039 in view of Di Rocco et al. of U.S. Patent No. 5,496,836.

The rejection is maintained for reason of the record.

Roberts-Lewis et al. teach it is known in the neurological art of pharmacology that chloroquine or hydroxychloroquine are used in the treatment of neurological disorders, namely Parkinson's disease, (see column 2, lines 22-34 and column 8, lines 40-60). Di Rocco et al. teach of treating movement disorders, such as Parkinson's disease, with the administration of cimetidine, (see column 5, lines 20-45 and from column 6, line 23 to column 7, line 11). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven,* 626 F.2d 846,850,205 USPQ 1069, 1072 (CCPA 1980). Moreover, it is well within the level of the skilled artisan to determine optimal modes and methods of administration as well as the procedures for making pharmaceutical compositions having the optimum therapeutic dosage while minimizing adverse and/or unwanted side effects.

8. **The Rejection Under Section 103(a) Over Bussy, Lim et ah and Di Rocco, et al**

Applicant's arguments, with respect to the rejection under 35 USC 103(a) have been fully considered but they are not persuasive.

Applicant argues Lim et al. show that chloroquine and related compounds inhibit acetylcholinesterase. It does not teach that these compounds are associated with anticholinergic activity. In fact the teaching of Lim et al. would lead one to believe that

chloroquine and related compounds were not associated with anticholinergic activity. Moreover, Bussy teaches only that certain anticholinergics have been used as treatments for Parkinson's Disease, namely trihexyphenidyl, benztropine, ethopropazine, biperiden, cycrimine, and procyclidine. It does not teach that any anticholinergic drug is useful as a treatment for Parkinson's Disease, nor that chloroquine is an anticholinergic drug. When combined with Lim et al., the references teach away from the use of chloroquine compounds to treat Parkinson's disease. This in not persuasive; Lim et al clearly discloses that Lim et al. compounds possessing the quinoline nucleus, including chloroquine, have long been associated with anticholinergic activity, (see page 527), see page 7 of the previous office action. Moreover, although Bussy teaches certain anticholinergics have been used as treatments for Parkinson's Disease, namely trihexyphenidyl, benztropine, ethopropazine, biperiden, cycrimine, and procyclidine, Bussy also refers to go to the next section about anticholinergics which states on page 724 that as a general rule, anticholinergic agents are estimated to improve parkinsonism's disease by about 20%. Therefore it would have been prima facie obvious to combine the reference taught by Bussy in view of Lim and Di Rocco to administer the two known compounds; cimetidine and chloroquine where each compound is known in the art to treat Parkinson's disease as stated in the previous office action. Therefore the rejection is maintained.

Claims 1-13 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Bussy, R. K., Editor-in-Chief, Merritt's Textbook of Neurolog~

Ninth Edition, pages 713-730 in view of Lim, L. Y. et al. of Clinical and Experimental Pharmacology & Physiology 12, 527-531, 1985 in further view of I Rocco et al. of U.S. Patent No. 5,496,836.

The rejection is maintained for reason of the record.

Bussy, R. K. teaches of treating parkinsonian syndromes, namely Parkinson's Disease and drug-induced Parkinsonism, which are movement disorders, (see page 713-716 and 727-730). In addition, Bussy, R. K. teach of various therapeutic treatments for Parkinson disease, namely anticholinergics, antihistamines, and antidepressants, including serotonin-uptake inhibitors, (see page 722), which provides the skilled artisan with motivation to utilize various types of compounds to treat parkinsonian syndromes, namely Parkinson's Disease and drug-induced Parkinsonism. Lim et al. teach that compounds possessing the quinoline nucleus, including chloroquine, have long been associated with anticholinergic activity, (see page 527). Moreover, Lim, L. Y. et al. provide the skilled artisan with the notion that compounds possessing the quinoline nucleus, including chloroquine, have long been associated with anticholinergic activity. Di Rocco et al. teach of treating movement disorders, such as Parkinson's Disease, with the administration of cimetidine, (see column 5, lines 20-45 and from column 6, line 23 to column 7, line 11). It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven,* 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Moreover, it is well within the level of the skilled artisan to determine optimal modes and methods of administration as well as the procedures for making pharmaceutical compositions having the optimum therapeutic dosage while minimizing adverse and/or unwanted side effects.

9. **The Double Patenting Rejection**

Applicant's arguments with respect to double patenting rejection have been fully considered and are persuasive. The double patenting rejection of has been withdrawn due to submission of a terminal disclaimer received on 09/01/2006 which is acknowledged the examiner.

9. **Exhibits A through O**

Exhibits A-O have been fully considered but they are not persuasive for the above reasons.

9. **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEAN CORNET whose telephone number is (571)270-7669. The examiner can normally be reached on Monday-Thursday 7.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JC/

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614